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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/666,471      | 09/19/2003  | Barry Pritchard      | AFP-PT009.1         | 8870             |

3624 7590 11/13/2006

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| EXAMINER |
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DESAI, HEMANT

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| ART UNIT | PAPER NUMBER |
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3721

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/666,471

Applicant(s)

PRITCHARD ET AL.

Examiner

Hemant M. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 37-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 and 47-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/10/04 & 5/19/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-36 and 47-67 in the reply filed on 10/11/2006 is acknowledged. The traversal is on the ground(s) that no serious burden exists in examining all of the claims in the application. The claims of Group I and Group II, as grouped by the Examiner, are so inter-related as to require a same field of search. This is not found persuasive because the restriction is deemed proper because the groups of inventions are distinct from each other as stated in the previous office action. Furthermore, since the groups are classified in different class/subclass, it is deemed that there is burden on the examiner if no restriction was required.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-9, 25-36, 47-52, 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al. (5484375) in view of Cicha et al. (5857309).

Owensby et al. disclose apparatus and method for attaching a tube segment to a bag by fusing them together comprising a tube inserter arranged to grip the tube segment and place the tube segment between the wall portions of the bag film, and at least one member for fusing the tube segment between the wall portions of the bag film

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so that the open end of the tube segment is in communication with the interior space in the bag (see col. 7, lines 43-67).

Owensby et al., as mentioned above, disclose all the claimed limitations, except the sterile processing chamber to sterilize the fitment and the bag. However, Cicha et al. teach to sterilize the fitment (50, fig. 1) and the bag (30, fig. 1) thereby providing more sterile packaging process that gives rise to a naturally extended shelf life for the product (see col. 2, lines 60-65). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the sterile processing chamber as taught by Cicha et al. in the apparatus and method of Owensby et al. for attaching a tube segment to a bag for providing more sterile packaging process that gives rise to a naturally extended shelf life for the product.

Regarding claims 2-9, Cicha et al. teach a tube (fitment) sterilization chamber (50, fig. 1) in which tubing (fitment) from a supply of tubing is introduced, the tube sterilization chamber being in communication with the sterile processing chamber and the sterilization chamber includes a hydrogen peroxide bath (see col. 3, lines 1-50).

Regarding claims 25-27, Owensby et al. disclose a bag film splitter (41, fig. 3) that separates the opposing wall portions of the bag film from one another at a tube insertion site prior to the inserter placing tube segment in position (see col. 7, lines 59-63).

Regarding claims 28-35, and 61-66 Owensby et al. disclose that the at least one member comprises at least one sealing jaw for heat sealing the open end of the tube segment between the wall portions of the bag film (see fig. 4).

Regarding claims 47-52, the modified method of Owensby et al. meets all the claimed limitations of claims 47-52.

4. Claims 10-24, 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owensby et al. and Cicha et al. as applied to claims 1 and 48 above, and further in view of Versteeg (4166412).

The modified apparatus and method of Owensby et al. meets all the limitations of claims 10-21, 53-58 except for a tube supply unwind stand with a supply of tubing. However, Versteeg discloses that it is known in the art to provide the tube supply unwind stand with a supply of tubing (118, fig. 14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube segment of Owensby et al. with the tube supply unwind stand with a supply of tubing in order to supply continuous supply of tube segments.

Regarding claims 22-24, and 59-60 Versteeg teaches that the inserter (121, fig. 13) comprises opposing jaws that are moveable toward one another to grip an end of tubing from supply of tubing prior to the tubing being cut (122, fig. 14) from the supply of tubing to form the tube segment.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claim 67 rejected under 35 U.S.C. 102(b) as being anticipated by Henfrey (3792799).

Henfrey discloses a method of attaching a tube to a bag (26, fig. 1), comprising placing a barbed fitment (22, fig. 3) into the bag prior to sealing the bag, locating the fitment in the bag, pressing a tube (10, figs. 3-4) over the fitment so that the fitment extends through the a sidewall of the bag, which meets all the claimed limitations.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant M. Desai whose telephone number is (571) 272-4458. The examiner can normally be reached on 6:30 AM-5:00 PM, Mon-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (571) 272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



HEMANT M. DESAI  
PRIMARY EXAMINER